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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,512	04/22/2004	Cristina M. Rondinone	7068.US.O1	7339

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/829,512	RONDINONE ET AL.	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1- 7 drawn to a method of identifying a kinase or phosphatase that degrades insulin receptor substrate (IRS-1) and reduces insulin-induced phosphorylation of protein kinase B (PKB), comprising transfecting a human hepatoma cell with a siRNA, classified in class 435, subclass 91.1.

II. Claims 12 drawn to a method of identifying a compound which inhibits a Kinase, wherein said kinase causes IRS-1 degradation, classified in class 435, subclass 91.1.

III. Claims 8-11, 14 and 15 drawn to a method of treating a condition in a mammal characterized by diminish uptake of glucose comprising administration to said mammal of a siRNA against a kinase, classified in class 435, subclass 91.1.

IV. Claims 8-11, 16 and 17 drawn to a method of treating a condition in a mammal characterized by diminish uptake of glucose comprising administration to said mammal of a siRNA against.a phosphatase, classified in 435, subclass 91.1.

V. Claim 13 drawn to a method of identifying a compound, which inhibits a Phosphatase, wherein said phosphatase causes IRS-1 degradation, classified in 435, subclass 91.1.

VI. Claims 18 and 19 drawn to a method of reducing IRS-1 degradation and increasing insulin-induced phosphorylation of PKB in a mammal comprising administration to said mammal of an agonist of the kinase, classified in class 435, subclass 91.1.

VII. Claims 20 and 21 drawn to a method of identifying a compound, which increases activity of a kinase, wherein activity of said kinase prevents IRS-1 degradation, classified in 435, subclass 91.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I or II or III or IV or V or VI or VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, each being used in different capacities, have different functions and produce different effects. For example invention of group III drawn to a method of treating a condition in a mammal characterized by diminished uptake of glucose can be done by other methods in addition to administering a siRNA against a kinase or phosphatase such as a proper diet. Additionally, the different inventions of Groups I or II or III or IV or V or VI or VII are drawn to distinct goals that are not required by any of the other groups, e.g., identifying a kinase or phosphate comprising transfecting a human hepatoma cell with a siRNA (Group I), identifying a compound, which increases activity of a kinase causes IRS-1 degradation (Group II), treating a condition in a

mammal by administration of a siRNA against a kinase (Group III), treating a condition in a mammal by administration of a siRNA against a phosphatase (Group IV) identifying a compound, which inhibits phosphatase which causes IRS-1 degradation (Group V), reducing IRS-1 degradation and increasing insulin-induced phosphorylation of PKB comprising administration to said mammal of an agonist of a kinase (Group VI) identifying a compound, which increases activity of a kinase causes IRS-1 degradation (Group VII). A search for prior art and consideration of patentability of all claims of Groups I or II or III or IV or V or VI or VII together does not necessary overlap with one another, thereby generating an undue burden in the examiner.

Species Restriction.

Should Group I be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

This application contains claims directed to the following patentably distinct species:

S6KB2, IKK2, PKC theta, pim 2, pyruvate dehydrogenase, PKC iota, PKC delta, UDP-N-acetylglucosamine-2-epimerimase/N- acetylmannosamine, CaMKl-like protein, DAPK2, casein kinase 1 delta, casein kinase 1 gamma 3, DCAMKLI, SnK Akin kinase, NP 067675, STKIO, MAGUK p55 member 2, oxidative-stress responsiveness 1, NP_ 060189, inositol 1, 3, 4 triphosphate 5-6 kinase, mitogen-activated protein kinase mitogen-activated protein kinase kinase (isoform 2b), phosphorylase kinase alpha 2, salt- inducible protein kinase, Jun kinase dystrophia myotonica protein kinase, CGPKI, MKK6, serine-threonine protein kinase PRP4 homolog, STE-2-1ike kinase, protein tyrosine kinase 9, and P38 delta and adenylate kinase 3 (alpha-like).

The species are independent or distinct because there are methods drawn to identifying kinases each kinase having different chemical structures; physical properties and biological functions with separate search as a result of containing different expressed genes or chemical compounds.

1) Applicant is required to choose one specifically named kinase as recited in claim 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 8 are generic.

Should Group II or III be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

This application contains claims directed to the following patentably distinct species:

S6KB2, IKKZ, PKC theta, pim 2, pyruvate dehydrogenase, PKC iota, PKC delta, UDP-N-acetylglucosamine-2-epimerimase/N-acetylmannosamine, CaMKI-like protein, DAPK2, casein kinase delta, casein kinase 1 gamma 3, DCAMKLI, SnK Akin kinase, NP 067675, STK10, MAGUK p55 member 2, oxidative-stress responsiveness 1, NP 060189, inositol 1, 3, 4 triphosphate 5-6 kinase, mitogen- activated protein kinase 4, mitogen-activated protein kinase 7, LIM kinase (isoform 2b), phosphorylase kinase alpha salt-inducible protein kinase, Jun kinase dystrophia myotonica protein kinase, CGPKI, MKK6, serine- threonine protein kinase PRPM homolog, STE-2-1ike kinase, protein tyrosine kinase 9, and P38 delta and adenylate kinase 3 (alpha-like).

The species are independent or distinct because there are methods drawn to of treating a condition in a mammal characterized by diminished uptake of glucose comprising administration of siRNA against a kinase each kinase having different chemical structures, physical properties and biological functions which separate search as a result of containing different expressed genes or chemical compounds.

2) Applicant is required to choose one specifically named kinase as recited in claim 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 8 are generic.

Should Group IIII be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

This application contains claims directed to the following patentably distinct species:

S6KB2, IKKZ, PKC theta, pim 2, pyruvate dehydrogenase, PKC iota, PKC delta, UDP-N- acetylglucosamine-2-epimerimase/N-acetylmannosamine, CaMKl-like protein, DAPKZ, casein kinase 1 delta, casein kinase 1 gamma 3, DCAMKLI, SnK Akin kinase, NP 067675, STKIO, MAGUK p55 member 2, oxidative-stress responsiveness 1, NP_ 060189, inositol 1, triphosphate 5-6 kinase, mitogen-activated protein kinase mitogen-activated protein kinase LIM kinase 2 (isoform 2b), phosphorylase kinase alpha 2, salt- inducible protein kinase, Jun kinase 1, dystrophia myotonica protein kinase, CGPKI, MKK6, serine-threonine protein kinase PRP4 homolog, STE-2-1ike kinase, protein tyrosine kinase 9, P38 delta and adenylate kinase 3 (alpha-like).

The species are independent or distinct because there are methods drawn to a method of reducing IRS-1 degradation and increasing insulin-induced phosphorylation of PKB in a mammal comprising administration to said mammal of an siRNA against a kinase each kinase having different chemical structures, physical properties and biological functions which separate search as a result of containing different expressed genes or chemical compounds.

3) Applicant is required to choose one specifically named kinase as recited in claim 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 8 are generic.

Should Group VI be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:

This application contains claims directed to the following patentably distinct species:

AXL, liver phosphofructokinase, death-associated kinase-3, galactokinase 1 and fyn-related kinase.

The species are independent or distinct because there are methods drawn to reducing IRS-1 degradation and increasing insulin-induced phosphorylation of PKB in a mammal comprising administration to said mammal of an agonist of the kinase each kinase having different chemical structures, physical properties and biological functions which separate search as a result of containing different expressed genes or chemical compounds.

4) Applicant is required to choose one specifically named kinase as recited in claim 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 8 are generic.

Should Group VII be elected, the claims of the elected group are generic to a plurality of disclosed patentable distinct species comprising:
This application contains claims directed to the following patentably distinct species:

AXL, liver phosphofructokinase, death-associated kinase-3, galactokinase 1 and fyn-related kinase.

The species are independent or distinct because there are methods drawn to identifying a compound, which increases activity of a kinase, wherein activity of said kinase prevents IRS-1 degradation, each kinase having different chemical structures, physical properties and biological functions which separate search as a result of containing different expressed genes or chemical compounds.

5) Applicant is required to choose one specifically named kinase as recited in claim 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 8 are generic.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these species are structurally distinct, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and/or consider patentability of all of the claims as presently pending.

Applicant is advised that the response to this requirement to be complete must include an species election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776 or the examiner's supervisor, Nguyen Dave, can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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